UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY and
DR. JOHN M. RODDY, her husband,
1833 NE 148 Avenue
Portland, OR 97230

Plaintiffs,

Civil Action No.: _____

vs.

MERCK & CO., INC.,
One Merck Drive
Whitehouse Station, NJ 08889
w/s/o CT CORPORATION
1025 Vermont Avenue, N.W.
Washington, DC 20005

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, VICTORIA G. RODDY and DR. JOHN M. RODDY, her husband, through their undersigned attorneys, sue Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiffs and Defendant. Plaintiffs are residents of the State of Oregon, and Defendant is incorporated and has as its primary business in the State

of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.

II. PARTIES

2. Plaintiff VICTORIA G. RODDY was born August 9, 1940. Plaintiff used FOSAMAX from approximately 2001 until approximately August 2005. Plaintiff VICTORIA G. RODDY was married to DR. JOHN M. RODDY and they were residents of the state of Oregon at all times material to this action.

3. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey.

4. Defendant is doing business and has regularly transacted business in the State of Oregon and the District of Columbia and continues to do so.

5. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.

6. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Oregon for the treatment of osteoporosis.

7. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Oregon and the District of Columbia .

8. Defendant expected, or should have expected, that its business activities could or

would have consequences within the State of Oregon and the District of Columbia.

III. SUMMARY OF THE CASE

9. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.

10. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff VICTORIA G. RODDY, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.

11. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff VICTORIA G. RODDY, other consumers, and the medical community.

12. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

13. As a result of Defendant's actions and inaction, Plaintiff VICTORIA G. RODDY was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

IV. FACTUAL BACKGROUND

14. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

15. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.

16. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

17. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (Actonel); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

18. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the

frequent and common occurrence of osteonecrosis of the jaw with the use of nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared an adverse event profile similar to that of the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

19. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

20. Merck also knew or should have known these factors combine to create a compromised vascular supply to the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

21. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

22. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

23. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw

and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

24. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

25. Since FOSAMAX was released, the FDA has received a number of reports of osteonecrosis of the jaw among users of FOSAMAX.

26. On August 25, 2004, the FDA posted its Office of Drug Safety ("ODS") Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

27. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that osteonecrosis of the jaw was a class effect that specifically extended to the oral bisphosphonate FOSAMAX.

28. As a result, the FDA recommended and stated that the labeling for FOSAMAX

should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

29. Rather than warn patients, and despite Defendant's knowledge of an increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.

30. FOSAMAX is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

31. Consumers, including Plaintiff VICTORIA G. RODDY, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.

32. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff VICTORIA G. RODDY, or the medical community, of such risks.

33. As a direct result, Plaintiff VICTORIA G. RODDY was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff VICTORIA G. RODDY requires and will in the future require ongoing medical care and treatment for the injuries she suffered as a result of taking FOSAMAX.

34. Plaintiff VICTORIA G. RODDY has suffered mental anguish as a result of knowing

the life-long complications she will suffer as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

35. Plaintiff VICTORIA G. RODDY was prescribed and began taking FOSAMAX in approximately 2001.

36. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

37. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury to the jaw.

38. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and has sustained permanent injuries and emotional distress.

39. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

40. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

41. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

42. As a result of Defendant's actions, Plaintiff and her prescribing and treating

physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

V. COUNTS

COUNT I: NEGLIGENCE

43. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

44. Defendant owed Plaintiff, VICTORIA G. RODDY, other consumers, and physicians a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

45. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and throughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

46. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

47. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

48. Plaintiff VICTORIA G. RODDY's spouse, DR. JOHN M. RODDY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident

to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT II: STRICT LIABILITY

49. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

50. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff VICTORIA G. RODDY.

51. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

52. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

53. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

54. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

55. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an

ordinary consumer could reasonably foresee or anticipate.

56. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, and or physicians, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

57. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

58. Plaintiff and or her physician(s) could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

59. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for

hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

60. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

61. Plaintiff VICTORIA G. RODDY's spouse, DR. JOHN M. RODDY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT III: BREACH OF EXPRESS WARRANTY

62. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

63. Defendant expressly represented to Plaintiff VICTORIA G. RODDY and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

64. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

65. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

66. Plaintiff VICTORIA G. RODDY, other consumers, and the medical community relied upon Defendant's express warranties.

67. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

68. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

69. Plaintiff VICTORIA G. RODDY's spouse, DR. JOHN M. RODDY, sustained a loss

of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT IV: BREACH OF IMPLIED WARRANTY

70. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

71. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

72. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

73. Defendant was aware that consumers, including Plaintiff VICTORIA G. RODDY, would use FOSAMAX for treatment of osteoporosis and for other purposes.

74. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

75. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

76. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

77. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

78. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

79. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

80. Plaintiff VICTORIA G. RODDY's spouse, DR. JOHN M. RODDY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT V: FRAUDULENT MISREPRESENTATION

81. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

82. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

83. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

84. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

85. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

86. Plaintiff VICTORIA G. RODDY, Plaintiff's doctors, and others relied upon the representations.

87. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

88. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

89. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

90. Plaintiff VICTORIA G. RODDY's spouse, DR. JOHN M. RODDY, sustained a loss

of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT VI: FRAUDULENT CONCEALMENT

91. Plaintiffs re-allege the above paragraphs as if fully set forth herein.

92. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

93. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

94. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

95. The concealment of information and the misrepresentations about FOSAMAX were

made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

96. Plaintiff VICTORIA G. RODDY, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

97. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff VICTORIA G. RODDY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

98. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

99. Plaintiff VICTORIA G. RODDY 's DR. JOHN M. RODDY, DR. JOHN M. RODDY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant, as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action; and

e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

Respectfully submitted,

AARON M. LEVINE & ASSOCIATES

_____

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VI. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

_____
Brandon J. Levine, #412130

Of Counsel:

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JS-44
(Rev.1/05 DC)

CIVIL COVER SHEET

I (a) PLAINTIFFS	DEFENDANTS
(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF **(EXCEPT IN U.S. PLAINTIFF CASES)**	COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT **(IN U.S. PLAINTIFF CASES ONLY)** NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED
(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)	ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION

(PLACE AN x IN ONE BOX ONLY)

1 U.S. Government Plaintiff

3 Federal Question (U.S. Government Not a Party)

2 U.S. Government Defendant

4 Diversity (Indicate Citizenship of Parties in item III)

III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	1	1	Incorporated or Principal Place of Business in This State	4	4
Citizen of Another State	2	2	Incorporated and Principal Place of Business in Another State	5	5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

A. *Antitrust*

410 Antitrust

B. *Personal Injury/ Malpractice*

310 Airplane
315 Airplane Product Liability
320 Assault, Libel & Slander
330 Federal Employers Liability
340 Marine
345 Marine Product Liability
350 Motor Vehicle
355 Motor Vehicle Product Liability
360 Other Personal Injury
362 Medical Malpractice
365 Product Liability
368 Asbestos Product Liability

C. *Administrative Agency Review*

151 Medicare Act

Social Security:
861 HIA ((1395ff)
862 Black Lung (923)
863 DIWC/DIWW (405(g)
864 SSID Title XVI
865 RSI (405(g)

Other Statutes
891 Agricultural Acts
892 Economic Stabilization Act
893 Environmental Matters
894 Energy Allocation Act
890 Other Statutory Actions (If Administrative Agency is Involved)

D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

E. *General Civil (Other)* OR F. *Pro Se General Civil*

Real Property
210 Land Condemnation
220 Foreclosure
230 Rent, Lease & Ejectment
240 Torts to Land
245 Tort Product Liability
290 All Other Real Property

Personal Property
370 Other Fraud
371 Truth in Lending
380 Other Personal Property Damage
385 Property Damage Product Liability

Bankruptcy
422 Appeal 28 USC 158
423 Withdrawal 28 USC 157

Prisoner Petitions
535 Death Penalty
540 Mandamus & Other
550 Civil Rights
555 Prison Condition

Property Rights
820 Copyrights
830 Patent
840 Trademark

Federal Tax Suits
870 Taxes (US plaintiff or defendant
871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
610 Agriculture
620 Other Food &Drug
625 Drug Related Seizure of Property 21 USC 881
630 Liquor Laws
640 RR & Truck
650 Airline Regs
660 Occupational Safety/Health
690 Other

Other Statutes
400 State Reapportionment
430 Banks & Banking
450 Commerce/ICC Rates/etc.
460 Deportation
470 Racketeer Influenced & Corrupt Organizations
480 Consumer Credit
490 Cable/Satellite TV
810 Selective Service
850 Securities/Commodities/ Exchange
875 Customer Challenge 12 USC 3410
900 Appeal of fee determination under equal access to Justice
950 Constitutionality of State Statutes
890 Other Statutory Actions (if not administrative agency review or Privacy Act

G. *Habeas Corpus/ 2255*	H. *Employment Discrimination*	I. *FOIA/PRIVACY ACT*	J. *Student Loan*
530 Habeas Corpus-General 510 Motion/Vacate Sentence	442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	895 Freedom of Information Act 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	152 Recovery of Defaulted Student Loans (excluding veterans)

K. *Labor/ERISA (non-employment)*	L. *Other Civil Rights (non-employment)*	M. *Contract*	N. *Three-Judge Court*
710 Fair Labor Standards Act 720 Labor/Mgmt. Relations 730 Labor/Mgmt. Reporting & Disclosure Act 740 Labor Railway Act 790 Other Labor Litigation 791 Empl. Ret. Inc. Security Act	441 Voting (if not Voting Rights Act) 443 Housing/Accommodations 444 Welfare 440 Other Civil Rights 445 American w/Disabilities-Employment 446 Americans w/Disabilities-Other	110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholder's Suits 190 Other Contracts 195 Contract Product Liability 196 Franchise	441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN

1 Original Proceeding | 2 Removed from State Court | 3 Remanded from Appellate Court | 4 Reinstated or Reopened | 5 Transferred from another district (specify) | 6 Multi district Litigation | 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** **NO**

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** **NO** If yes, please complete related case form.

DATE **SIGNATURE OF ATTORNEY OF RECORD**

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44

Authority for Civil Cover Sheet

The **JS-44** civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff is resident of Washington, D.C.; 88888 if plaintiff is resident of the United States but not of Washington, D.C., and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section **II**.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of case.

VI. CAUSE OF ACTION: Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASES, IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY, et al,	]	
	]	
Plaintiffs,	]	
	]	
v.	]	**Civil Action No.: 08-723 (RJL)**
	]	**Next Event:**
MERCK & CO. INC.,	]	
	]	
Defendant.	]	

NOTICE OF APPEARANCE

TO THE CLERK OF THE COURT AND ALL PARTIES OF RECORD:

Pursuant to LCvR 83.6, please enter the appearance of Aaron M. Levine of AARON M. LEVINE & ASSOCIATES as counsel for plaintiffs, VICTORIA RODDY and JOHN M. RODDY, in the above-referenced matter.

Respectfully submitted,

AARON M. LEVINE & ASSOCIATES

/s/ Aaron M. Levine

AARON M. LEVINE, #7864
1320 19th Street, N.W., Suite 500
Washington, DC 20036
202-833-8040
Fax: 202-833-8046

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY, et al,	]	
	]	
Plaintiffs,	]	
	]	
v.	]	**Civil Action No.: 08-723 (RJL)**
	]	**Next Event:**
MERCK & CO. INC.,	]	
	]	
Defendant.	]	

NOTICE OF APPEARANCE

TO THE CLERK OF THE COURT AND ALL PARTIES OF RECORD:

Pursuant to LCvR 83.6, please enter the appearance of Brandon J. Levine of AARON M. LEVINE & ASSOCIATES as counsel for plaintiff, VICTORIA RODDY and JOHN M. RODDY, in the above-referenced matter.

Respectfully submitted,

AARON M. LEVINE & ASSOCIATES

/s/ Brandon J. Levine

BRANDON J. LEVINE, #412130
1320 19th Street, N.W., Suite 500
Washington, DC 20036
202-833-8040
Fax: 202-833-8046

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY and **DR. JOHN M. RODDY, her husband** **1833 NE 148 Avenue** **Portland, OR 97230** **Plaintiffs,** **v.** **MERCK & CO., INC.** **One Merck Drive** **Whitehouse Station, NJ 08889** **w/s/o CT CORPORATION** **1025 Vermont Avenue, N.W.** **Washington, DC 20005** **Defendant.**	)	**Civil Case No. 08cv0723 (RJL)**

CASE MANAGEMENT ORDER

May 5, 2008

This case has been assigned to the calendar of Judge Richard Leon. The plaintiff shall immediately serve this Order on all parties, including any new parties to the action. If this case came to the Court by a Petition for Removal, the removing defendant(s) shall serve this order on all other parties.

Upon the Court's motion, it is hereby

ORDERED that within 30 days of all defendants answering the complaint or filing other motions under Rule 12(b) of the Federal Rules of Civil Procedure, or within 30 days of the issuance of this order if an answer or Rule 12(b) motion has already been filed, the parties shall

confer pursuant to Federal Rule of Civil Procedure 26(f) and Local Civil Rule 16.3.[1] No later than fourteen days following that meeting, counsel shall submit: (1) their Joint Meet and Confer Statement addressing all topics listed in Local Civil Rule 16.3©; and (2) a proposed scheduling order(s) in accordance with Rule 16.3(d). Counsel are also directed to include in their Joint Meet and Confer Statement a one-page statement of the facts of the case and the statutory basis for all causes of action and defenses. Once the Joint Meet and Confer Statement has been filed, the Court will schedule an initial status conference; and it is further

ORDERED that all counsel must familiarize themselves with the Federal Rules of Civil Procedure, particularly Federal Rules of Civil Procedure 16 and 26, and the Local Rules of the District of Columbia, "to secure the just, speedy, and inexpensive determination of [this] action," Fed. R. Civ. P. 1;[2] and it is further

ORDERED that parties comply with the following chambers practices and policies:

1. **Courtroom Proceedings**: All courtroom proceedings, unless otherwise indicated, will be conducted in Courtroom 18 on the sixth floor of the E. Barrett Prettyman United States Courthouse, 333 Constitution Avenue, N.W., Washington, D.C. 20001. Non-courtroom conferences and meetings will be held in Judge Leon's chambers unless otherwise specified.

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[1] The May 17, 2001 amendment to Local Civil Rule 16.3 sets forth additional categories of proceedings that are exempted from this Rule's meet and confer requirements. If counsel's proceeding is exempt from the local rule's requirements, counsel for both parties shall jointly prepare and submit a statement to the Court indicating whether they believe the matter will be resolved solely through the filing of dispositive motions and proposing a scheduling timeline for the filing of such motions to the Court. Counsel shall also indicate whether or not they believe an appearance before the Court will be necessary prior to resolution of the dispositive motions.

[2] The Local Civil Rules are available at "http:\\www.dcd.uscourts.gov".

2. **Communications with Chambers:** Counsel shall not contact the Court or its chambers regarding non-emergency matters by telephone, facsimile, letter, or by any other means. Chambers may not provide legal advice or comment on the status of any pending motions. Counsel may contact the Courtroom Deputy Clerk regarding emergency scheduling matters.

3. **Proposed Orders**: All motions, whether filed through the Electronic Filing System (ECF) or otherwise, must be accompanied by a proposed order setting forth the relief or action sought. Under no circumstances shall the signature line appear alone on a page of the proposed order.

4. **Rescheduling Court Proceedings:** Requests for continuances of court proceedings are strongly discouraged because of the inconvenience they cause to the Court. If counsel seeks to change a previously scheduled hearing date, counsel is directed to submit a written motion at least four days prior to the proceeding. In the event of an emergency, the four-day rule will be waived but counsel must still file a written motion in support of their request. The written motion must:
   a. demonstrate good cause for the continuance;
   b. state the opposing party's position on the continuance; and
   c. propose at least three alternative dates and times that would be convenient for all parties in the case. If counsel's suggested dates and times are not available on the Court's calendar, an alternative of the Court's choosing will be selected.

5. **Court Appearances by Counsel:** An attorney with authority to make scheduling decisions must appear on behalf of the parties at all court appearances. In addition, counsel must have their calendars and the calendars of any necessary co-counsel available with them for possible scheduling of future events related to the case. In the event that counsel is not a member of the Bar of this Court and is located outside the District, local

counsel[3] must be available to appear with the necessary authority to make scheduling decisions on behalf of all parties and counsel in the case.

6. **Motions for Extensions of Time to File Pleadings:** Motions for extension of time to file pleadings are strongly discouraged unless both parties consent. Counsel seeking an extension of time must file a written motion and a proposed order. Such a motion must include:

   a. the number of previous extensions requested and granted to each party;

   b. the specific ground(s) for the motion; a statement of the effect that the Court's granting of the motion will have on all other previously scheduled deadlines;

   c. in cases where the motion seeks to extend the deadline for a dispositive motion, a suggested timeline for the filing of the opposition[4] and reply; and

   d. pursuant to Local Civil Rule 7(m), the moving party shall include a statement of opposing counsel's position on the motion.

   Failure to comply with the Local Civil Rules or this Order may result in rejection of the request. The Court grants such motions only upon a showing of good cause, focusing on the diligence of the party seeking the continuance and any prejudice that may result if the Court denies the continuance.[5]

7. **Pleadings:** Every pleading signed by an attorney shall, in conformity with Local Civil Rule 5.1(e), contain the name, address, telephone number, fax number, and bar identification number of the attorney and, where applicable, local counsel.

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[3] LCvR 83.2© requires that an attorney who is not a member of the Bar of this Court must obtain local counsel that is a member in good standing of this Court.

[4] The deadline for the opposition should be suggested only after consulting with opposing counsel.

[5] *See Jackson v. Finnegan, Henderson, Farabow, Garrett & Dunner,* 101 F.3d 145 (D.C. Cir. 1996).

8. **Settlement and Alternative Dispute Resolution:** In order to reduce litigation expenses and delay, to eliminate the anxiety of trial and the risk of an unsatisfactory outcome, it is desirable that settlement occur as early as possible in the litigation process. The Court is available to assist the parties in pursuing settlement early in the process. However, the Court will not delay trial so that the parties may participate in settlement discussions on the eve of trial.

It shall be the norm for all cases to be referred for some form of alternative dispute resolution (ADR). Pursuant to Rule 16.3, the parties' Joint Meet and Confer Statement should address the potential benefit of ADR to their case, what steps should be taken to facilitate ADR, and the point during litigation at which ADR would be most appropriate. In considering what form of alternative dispute resolution the parties think the case is most suited, counsel are reminded that their options include mediation (either with a private firm or a Magistrate Judge), arbitration, early neutral evaluation, summary jury trial, or any other form of alternative dispute resolution that can be tailored to the needs of their case. If the parties believe that the case is not a candidate for alternative dispute resolution, they should provide the Court with an explanation of their position.

9. **Stipulations of Dismissal:** Parties must submit a signed copy that includes a signature line for the Court. Under no circumstances shall the signature line appear alone on a page of the proposed order.

SO ORDERED.

RICHARD J. LEON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY and	:	**Case No. 1:08-CV-00723**
DR. JOHN M. RODDY	:	**Assigned to: Richard J. Leon**
	:	
Plaintiffs,	:	**JURY TRIAL DEMANDED**
	:	
v.	:	
	:	
MERCK & CO., INC.,	:	
One Merck Drive	:	
Whitehouse Station, NJ 08889-0100	:	
	:	
Defendant.	:	

DEFENDANT MERCK & CO., INC.'S ANSWER TO COMPLAINT

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorney, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

I. JURISDICTION AND VENUE

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Merck is without knowledge as to the allegations in the third sentence of Paragraph 1, but for jurisdictional purposes only, admits that the Plaintiffs seek in excess of $75,000.

II. PARTIES

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 2.

3. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 3.

4. Merck is without knowledge as to what is meant by the phrase "regularly transacted," so the allegations in Paragraph 4 are denied.

5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 5 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

6. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 6 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 6.

7. Merck is without knowledge as to what is meant by the phrase "substantial revenue," so the allegations in Paragraph 7 are denied.

8. Merck is without knowledge as to what is meant by "consequences," so the allegations in Paragraph 8 are denied.

III. SUMMARY OF THE CASE

9. Merck denies each and every allegation of Paragraph 9, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13.

IV. FACTUAL BACKGROUND

14. Merck denies each and every allegation of Paragraph 14, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

15. Merck denies each and every allegation of Paragraph 15, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 15 inconsistent with that prescribing information.

16. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing

information and denies any allegations in Paragraph 16 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 16 with respect to Aredia and Zometa inconsistent with that prescribing information.

17. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 17 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 17 with respect to Aredia, Boniva, Actonel, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30, except that Merck admits that Fosamax product sales in 2007 amounted to approximately $3.05 billion.

31. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34.

35. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 35.

36. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

V. COUNTS

COUNT I: NEGLIGENCE

43. Merck repleads its answers to Paragraphs 1 through and including 42, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

44. The allegations in Paragraph 44 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

45. Merck denies each and every allegation of Paragraph 45, including each and every allegation contained in subparts (a) through (f).

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

COUNT II: STRICT LIABILITY

49. Merck repleads its answers to Paragraphs 1 through and including 49, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

50. Merck denies each and every allegation of Paragraph 51, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

51. Merck denies each and every allegation of Paragraph 51, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

52. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

COUNT III: BREACH OF EXPRESS WARRANTY

62. Merck repleads its answers to Paragraphs 1 through and including 61, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

63. Merck denies each and every allegation of Paragraph 63, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

COUNT IV: BREACH OF IMPLIED WARRANTY

70. Merck repleads its answers to Paragraphs 1 through and including 70, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

71. Merck denies each and every allegation of Paragraph 71, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

72. Merck denies each and every allegation of Paragraph 72, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a

prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

COUNT V: FRAUDULENT MISREPRESENTATION

81. Merck repleads its answers to Paragraphs 1 through and including 80, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

82. Merck denies each and every allegation of Paragraph 82, including each and every allegation contained in subparts (a) through (b).

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

COUNT VI: FRAUDULENT CONCEALMENT

91. Merck repleads its answers to Paragraphs 1 through and including 90, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

92. Merck denies each and every allegation of Paragraph 92, including each and every allegation contained in subparts (a) through (b).

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

GLOBAL PRAYER FOR RELIEF

Merck denies that Plaintiffs are entitled to any of the relief requested in their Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States, Oregon, and District of Columbia Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are barred because Plaintiffs did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling

for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-FIFTH AFFIRMATIVE DEFENSE

The substantive law of Oregon applies to Plaintiffs' claims.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, may not exceed the limitations within ORS 31.710.

In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: May 22, 2008

Respectfully submitted,

VENABLE LLP

By: /s/
Michael B. MacWilliams
D.C. Bar No. 453549

Two Hopkins Plaza, Suite 1800
Baltimore, Maryland 21201
(410) 244-7400

Attorney for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 22nd day of May, 2007, a copy of Defendant Merck & Co., Inc.'s Answer to Complaint was filed electronically. Notice of electronic filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/
Michael B. MacWilliams

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VICTORIA RODDY and	:	**Case No. 1:08-CV-00723**
DR. JOHN M. RODDY	:	**Assigned to: Richard J. Leon**
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
MERCK & CO., INC.,	:	
One Merck Drive	:	
Whitehouse Station, NJ 08889-0100	:	
	:	
Defendant.	:	

DEFENDANT MERCK & CO., INC.'S LOCAL RULE 7.1 DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTERESTS

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorney submits this Certificate required by Local Rule 7.1 of the Local Rules of the United States District Court for the District of Columbia, and states as follows:

I, the undersigned, counsel of record for Merck & Co., Inc. ("Merck"), certify that to the best of my knowledge and belief, there are no parent companies, subsidiaries, or affiliates of Merck that have any outstanding securities in the hands of the public.

These representations are made in order that judges of this Court may determine the need for recusal.

Respectfully submitted,

VENABLE LLP

By: /s/
Michael B. MacWilliams
D.C. Bar No. 453549

Two Hopkins Plaza, Suite 1800
Baltimore, Maryland 21201
(410) 244-7400

Attorney for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 22nd day of May, 2007, a copy of Defendant Merck & Co., Inc.'s Local Rule 7.1 Disclosure of Corporate Affiliations and Financial Interests was filed electronically. Notice of electronic filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/
Attorney for Defendant

08 CV 5205

JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

MAY 15 2008

FILED
CLERK'S OFFICE

JUDGE KEENAN

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

MDL No. 1789

SD
6/6/08

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO-56)

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 126 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION MDL No. 1789

SCHEDULE CTO-56 - TAG-ALONG ACTIONS

DIST.	DIV.	C.A. #	CASE CAPTION
ARIZONA			
~~AZ~~	~~2~~	~~08-832~~	~~Gloria Kopecky, et al. v. Merck & Co., Inc., et al.~~ Opposed 5/27/08
DISTRICT OF COLUMBIA			
1 DC	1	08-723	Victoria Roddy, et al. v. Merck & Co., Inc.
UTAH			
2 UT	2	08-340	Joseph Hebert, et al. v. Merck & Co., Inc.
3 UT	2	08-341	Vickie Jones v. Merck & Co., Inc.
4 UT	2	08-342	Darlene Nelson, et al. v. Merck & Co., Inc.

UNITED STATES DISTRICT COURT
Southern District of New York
Office of the Clerk
500 Pearl Street
New York, N.Y. 10007
(212)805-0136

J. Michael McMahon
Clerk
DISTRICT OF COLUMBIA

Date: 6/6/2008

In Re: FOSAMAX PRODUCTS

MDL 1789

Your Docket #
08 -723

S.D. OF N.Y.
08 CV 5205

Dear Sir:

Enclosed is a certified copy of the order of the Judicial Panel on Multidistrict Litigation, transferring the above entitled action presently pending in your court, to the Southern District of New York and assigned to Judge KEENAN for coordinated or consolidated pretrial processing pursuant to 28 USC 1407.

Please return the copy of this letter when transmitting YOUR FILE and a CERTIFIED COPY OF THE DOCKET SHEET.

Sincerely,
J.Michael McMahon

By: PHYLLIS ADAMIK
MDL Unit
(212) 805-0646